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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,743	07/21/2003	David T. Hung	12.026011-DIV	4720

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,743	HUNG, DAVID T.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-20,25,26 and 29-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *13-20, 25, 26 and 29-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Hung

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 14, 15, 19 and 20, drawn in part to a method for identifying a patient having breast cancer or breast precancer comprising determining the presence of a marker comprising an expression product of a gene encoding a nuclear matrix protein, wherein the expression product is a nucleic acid, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single nuclear matrix protein from Claim 17 (i.e. from Lamin A, Lamin B, Lamin C, a peripheral matrix protein, nuclear mitotic spindle apparatus protein (NuMA), topoisomerase II, and an internal nuclear matrix protein). This election should not be construed as an election of species. This is a restriction requirement. Each of the nuclear matrix proteins is a structurally and functionally distinct molecule. The method and reagents used to detect one nuclear matrix protein is distinct from the other, therefore, searching is not coextensive (see paragraph 3, below).

II. Claim 14, 16 and 18, drawn to drawn in part to a method for identifying a patient having breast cancer or breast precancer comprising determining the presence of a marker comprising an expression product of a gene

encoding a nuclear matrix protein, wherein the expression product is a polypeptide, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single nuclear matrix protein from Claim 17 (i.e. from Lamin A, Lamin B, Lamin C, a peripheral matrix protein, nuclear mitotic spindle apparatus protein (NuMA), topoisomerase II, and an internal nuclear matrix protein). This election should not be construed as an election of species. This is a restriction requirement. Each of the nuclear matrix proteins is a structurally and functionally distinct molecule. The method and reagents used to detect one nuclear matrix protein is distinct from the other, therefore, searching is not coextensive (see paragraph 3, below).

III. Claims 30-40, drawn to a method for identifying a patient having breast cancer or breast precancer comprising determining the presence of a marker, classified in class 435, subclass 4.

If applicants elect this group for prosecution on the merits, applicants are required to elect a single marker from Claim 30. Moreover, applicants are further required to elect:

(a) a single type of chemokine from claim 33, i.e. from C-C type and C-X-C type chemokine if applicants elect chemokine as a cancer maker;

(b) a single cytokeratin from claim 34, i.e. from keratin 14, B1, KA1, KA4 and 312C8-1 if applicants elect cytokeratin as a cancer marker;

(c) a single member of the FGF family from claim 35, i.e. from FAF1-18, IGF-II, platelet-derived growth factor (PDGF), keratinocyte growth factor (KGF), and epithelial growth factor (EGF) if applicants elect a member of the FGF family as a cancer marker;

(d) a single cadherin from claim 38, i.e. from alpha and beta 3 integrin if applicants elect cadherin as a cancer marker;

(f) a single cancer antigen from claim 39, i.e. from Ki-67, Ki-S1, p53, nm23, bcl-2, p21 ras, cyclones, and pS2 if applicants elect a cancer antigen as a cancer marker.

This election should not be construed as an election of species. This is a restriction requirement. Each of the markers is a structurally and functionally distinct molecule. The method and reagents used to detect one marker is distinct from the other, therefore, searching is not coextensive (see paragraph 3, below).

2. Claims 13, 17, 25, 26 and 29 are linking claims which link groups I and II together. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP j 804.01.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. Inventions I-III are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material and comprises different methodological steps. Moreover, the methodology and materials necessary for detecting the nucleic acid of a nuclear matrix protein, a polypeptide of a nuclear matrix protein, and a marker differ significantly for each of the materials. For example, the assay used for detecting a nucleic acid is distinct from one used for detecting a protein. Therefore, the methods of Groups I-III are patentably distinct. Furthermore, the distinct steps and products require separate and distinct

searches. The inventions of Groups I-III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-III together.

Applicants are further required to elect a single nuclear matrix protein or single marker because the method for identifying a patient having breast cancer or breast precancer comprising determining one nuclear matrix protein, or one cancer marker is distinct from the method for identifying a patient having breast cancer or breast precancer comprising determining another nuclear matrix protein or another marker. Each of the nuclear matrix proteins or markers is structurally and functionally distinct molecule. The reagents used to detect one nuclear matrix protein or one marker is distinct from the other nuclear matrix protein or the other marker. Therefore, they are distinct. Moreover, the distinct steps and products require separate and distinct searches. Therefore, searching all the nuclear matrix proteins or cancer markers together will impose serious burden.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species:

(a) cathepsin D, cathepsin B and cathepsin L.

(b) HSP27, HSP90 alpha, and HSP90 beta.

The species are independent or distinct because they are all structurally and functionally distinct molecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from (a) or (b) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 30 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
April 25, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAM